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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,804	04/17/2001	Gebre-mariam Mesfin	6267.N	6782

7590

06/18/2003

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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/18/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/836,804

Applicant(s)

MESFIN ET AL.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on April 3, 2003 in Paper No. 14 wherein claims 1-12 have been amended. Currently, claims 1-12 are pending in this application.

Applicant's amendment amending claims 1-12, filed April 3, 2003 in Paper No. 14 with respect to the rejection made under 35 U.S.C. 112 first paragraph for lack of scope of enablement, for the methods for preventing osteoporosis, bone resorption or other bone disease in a vertebrate mammal of record stated in the Office Action dated January 29, 2003 has been fully considered and is found persuasive to remove the rejection since the recitation "preventing" has been removed.

Therefore, the said rejection is withdrawn.

Applicant's amendment amending claims 1-12, filed April 3, 2003 in Paper No. 14 with respect to the rejection made under 35 U.S.C. 112 second paragraph for indefinite expressions, "other bone disease" and "characterized by" in claims 1 and 7 of record stated in the Office Action dated January 29, 2003 has been fully considered and is found persuasive to remove the rejection since these expressions have been removed.

Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batts et al. (WO 9925344) for reasons of record stated in the Office Action dated January 29, 2003.

Applicant's remarks filed on April 3, 2003 in Paper No. 14 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

First, Applicant asserts that none of the 6 examples disclosed in Batts et al. are as described in this application. Contrary to Applicant's assertion, all 6 example compounds clearly read on the structural formula I in Batts and the 6 compounds of Batts are the particular species (compounds) of the genus of formula I.

Secondly, Applicant disagrees that arthritis is known to be associated with bone destruction. Applicant further argues that "Batts et al. uses the term arthritis in the context of a disease with inflammatory basis not in the context of a disease associated with bone loss". Nevertheless, Batts et al. clearly teaches that arthritis, inflammation of the joint tissues, including bacterial infection (septic arthritis), degeneration of articular

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surfaces (osteoarthritis), and rheumatoid arthritis. One of ordinary skill in the art would recognize that these arthritis taught by Batts are known to be tightly associated with bone diseases, osteoporosis and bone resorption, to induce bone destruction, and to stimulate bone matrix loss. The examiner's position supported by the review article by Nair et al. (of record), especially Fig. 1-3 at page 2372-2373, and the Merck Manual of Diagnosis and Therapy (16th ED) at page 412-413 (see attached copy). Hence, with or without these two references, the instant claims are prima facie obvious as discussed above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hester et al. (WO 9854161) in view of Nair et al. for reasons of record stated in the Office Action dated January 29, 2003.

Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (WO 9912914) in view of Nair et al. for reasons of record stated in the Office Action dated January 29, 2003.

Applicant's remarks filed on April 3, 2003 in Paper No. 14 with respect to these rejections made under 35 U.S.C. 103(a) of record in the previous Office Action have

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been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as discussed below.

Again, Applicant argument that treating bone destroying infection would not be obvious to treat osteoporosis and bone resorption, is not found convincing. As discussed above and in the previous Office Action, bone destroying infection or septic arthritis (bacterial infection) is known to tightly associated with bone diseases, osteoporosis and bone resorption, to induce bone destruction, and to stimulate bone matrix loss.

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

As discussed in previous Office Actions January 29, 2003 and July 2, 2002, Applicant's results on "Use of Compounds" of the specification at pages 44-45 herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive for the reasons below. The example herein merely demonstrate the employment of one particular compound within the instant claims in the treatment for increasing bone mass and density. Thus, the evidence in the example is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the active compounds in the claimed methods of treating various bone diseases herein. See MPEP § 716.02(d). Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

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For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejections are adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877.

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The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
June 4, 2003



SREENI PADMANABHAN
PRIMARY EXAMINER

6/16/03